IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE ORPHAN THERAPIES LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH, Plaintiffs, v. FRESENIUS KABI USA, LLC and SANDOZ INC., Defendants.	)	C.A. No. 15-1102 (GMS) CONSOLIDATED

[PROPOSED] STIPULATED PROTECTIVE ORDER

WHEREAS Plaintiffs Shire Orphan Therapies LLC and Sanofi-Aventis Deutschland GmbH (collectively "Plaintiffs") and Defendants Fresenius Kabi USA, LLC ("Fresenius") and Sandoz Inc. ("Sandoz") (collectively "Defendants") are currently litigating the present patent infringement Actions, which are likely to involve discovery of documents and testimony containing trade secrets and other confidential research, development, regulatory, and commercial information of the parties to these Actions and third parties, including confidential and commercially sensitive information relating to business strategies, manufacturing and distribution capabilities, sales, costs, pricing, profitability, customers, suppliers, and other business and financial data; and

WHEREAS this confidential information may be disclosed in providing initial disclosures, responding to written discovery requests, producing documents, providing testimony by way of deposition, conducting motion practice before the Court or otherwise in these Actions, and must be protected in order to preserve the legitimate business interests of the parties; and

WHEREAS good cause exists for entry of this Protective Order, *see* Fed. R. Civ. P. 26(c), *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994); and

WHEREAS the parties in their business practices have gone to great lengths to safeguard and protect the confidentiality of the documents and information, and the disclosure of which would pose a substantial risk of irreparable harm to the producing party's legitimate proprietary interests; and

WHEREAS this Protective Order provides reasonable restrictions on the disclosure of such sensitive materials of a confidential nature; and

WHEREAS all parties agree to the terms of this Protective Order to protect their confidential documents and information; and

THEREFORE, in view of the foregoing and because the parties hereto, by and through their respective counsel, have stipulated to the entry of the following Protective Order pursuant to Federal Rule of Civil Procedure 26(c), and the Court having determined that good cause exists for the entry of this Protective Order,

IT IS HEREBY STIPULATED AND ORDERED THAT the following procedures shall be employed and the following restrictions shall govern the handling of documents, depositions, pleadings, exhibits, and all other information exchanged by the parties in these Actions, or provided by or obtained from non-parties in these Actions:

1. Any party to these Actions and any third party shall have the right, subject to this Protective Order, to designate as "Confidential" any information, document, or thing, or portion of any document or thing: (a) that the producing party believes is not publicly known and which the producing party would not normally reveal to third parties, or that if disclosed, would require such third parties to maintain in confidence; or (b) that the producing party believes in good faith

is protected by a right to privacy under federal or state law or any other applicable privilege or right related to confidentiality or privacy, including any material within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G). Any party to these Actions or any third party who, subject to this Protective Order, produces or discloses any material designated as Confidential, including without limitation any information, document (which includes "electronically stored information," as that phrase is used in Federal Rule of Civil Procedure 34), tangible thing, interrogatory answer, admission, contention, pleading, or testimony, shall mark the same on every page or image with the foregoing or similar legend: "CONFIDENTIAL" or "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER" (hereinafter "Confidential").

2. Any party to these Actions and any third party shall have the right, subject to this Protective Order, to designate as "Highly Confidential" any information, document, or thing, or portion of any document or thing that contains highly sensitive business or personal information, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of the designating party. Such information includes the producing party's: (a) competitive business or highly sensitive commercial information (including, for example, business plans, business strategies, negotiations, due diligence, and license agreements); (b) financial information (including, for example, budgeting, accounting, sales figures and advertising expenditures); (c) business relationship information (including, for example, information pertaining to potential and/or existing customers, competitors, suppliers, distributors, affiliates, subsidiaries, and parents); (d) personnel information (including, for example, compensation, evaluations and other employment information); (e) technical and research and development information (including, for example, laboratory notebooks, meeting minutes, development reports, testing records, study protocols, research plans, patent prosecution

documents not filed with any Patent Office, market and demographic research, and product and advertising development); and (f) non-public regulatory information and information concerning drug applications and commercial products, and non-public communications with the United States Food and Drug Administration. Any party to these Actions or any third party who produces or discloses material designated as Highly Confidential, subject to this Protective Order, including without limitation any information, document (which includes "electronically stored information," as that phrase is used in Federal Rule of Civil Procedure 34), tangible thing, interrogatory answer, admission, pleading, or testimony, shall mark the same on every page or image with the foregoing or similar legend: "HIGHLY CONFIDENTIAL" or "HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER" (hereinafter "Highly Confidential").

3. All Confidential and Highly Confidential material shall be used by the receiving party solely for purposes of these Actions, shall not be used by the receiving party for any business, commercial, competitive, personal or other purpose, and shall not be disclosed by the receiving party to anyone other than those set forth in Paragraph 5 (for Confidential information) and Paragraph 6 (for Highly Confidential information), unless and until the restrictions herein are removed either by written agreement of counsel for the parties, or by Order of the Court. It is, however, understood that counsel for a party may give advice and opinions to his or her client relating to the above-captioned Actions based on his or her evaluation of Confidential or Highly Confidential material, provided that such advice and opinions shall not reveal the content of the Confidential or Highly Confidential material except by prior written agreement of counsel for the parties, or by Order of the Court. Nothing herein shall prohibit communications with the U.S.

Food and Drug Administration or the United States Patent and Trademark Office regarding solely the status of these Actions.

4. Where electronic files and documents are produced in native electronic format, such electronic files and documents shall be designated for protection under this Protective Order by appending Confidential or Highly Confidential to the file names or by any other reasonable method. When electronic files or documents produced in native electronic format are printed for use at deposition, in a court proceeding, or for the provision in printed form to an expert or consultant, the party printing the electronic files or documents produced in native electronic format shall affix a Confidential or Highly Confidential legend to the printed document and include the production number associated with the native file.

5. Confidential material and the contents of Confidential material may be disclosed only to the following individuals under the following conditions:

a. Outside counsel (herein defined as a party's outside counsel of record, including necessary paralegal, secretarial, and clerical personnel assisting such counsel, including but not limited to photocopying and graphics services) who agree to the prosecution bar in paragraph 16;

b. Jury consultants, mock judges/jurors, and third-party graphics/trial support vendors retained by outside counsel who have signed the undertaking attached as Exhibit A to this Protective Order;

c. Subject to the provisions of Paragraph 7 of this Protective Order, two in-house counsel for a party who have signed the undertaking attached as Exhibit A to this Protective Order and who agree to the prosecution bar in paragraph 16;

d. Stenographers and videographers recording testimony concerning the information;

e. Subject to the provisions of Paragraph 8 of this Protective Order, experts and consultants and their staff whom a party employs for purposes of these Actions only; and

f. The Court and personnel assisting the Court.

6. Highly Confidential material and the contents of Highly Confidential material may only be disclosed to any person identified in Paragraphs 5(a), (b), (d), (e), and (f).

7. A party may not disclose Confidential information to an in-house counsel pursuant to Paragraph 5(c) of this Protective Order until after the in-house counsel has signed an undertaking in the form of Exhibit A to this Protective Order. At least five (5) business days before the first disclosure of Confidential information to an in-house counsel, the party obtaining the undertaking must serve it via e-mail on all other parties. If the producing party has good cause to object to the disclosure, it must serve the party proposing to make the disclosure with a written objection within five (5) business days after service of the identification. Unless the parties resolve the dispute within five (5) business days after service of the objection, or a longer period if the parties so agree, the producing party must move the Court promptly for a ruling, and the Confidential information may not be disclosed to the in-house counsel without the Court's approval.

8. A party may not disclose Confidential or Highly Confidential information to an expert or consultant pursuant to Paragraph 5(e) or Paragraph 6 of this Protective Order until after the expert or consultant has signed an undertaking in the form of Exhibit A to this Protective Order. At least five (5) business days before the first disclosure of Confidential or Highly

Confidential information to an expert or consultant (or member of their staff), the party proposing to make the disclosure must serve by email on all other parties a written identification of the expert or consultant and: (i) the expert's or consultant's signed undertaking in the form of Exhibit A to this Protective Order; (ii) a copy of his or her curriculum vitae; (iii) if not already disclosed in the curriculum vitae, a general statement of any prior or current professional relationship (e.g., a consulting, legal, contractual, or advisory relationship) concerning bradykinin antagonists with any party in these Actions other than the party whose Confidential or Highly Confidential information is proposed to be disclosed; and (iv) a list of all other cases in which, during the previous four (4) years, the expert or consultant testified at trial or by deposition. If the producing party has good cause to object to the disclosure (which does not include challenging the qualifications of the expert or consultant), it must serve the party proposing to make the disclosure with a written objection within five (5) business days after service of the identification. Unless the parties resolve the dispute within five (5) business days after service of the objection, or a longer period if the parties so agree, the producing party must move the Court promptly for a ruling, and the Confidential or Highly Confidential information may not be disclosed to the expert or consultant without the Court's approval.

9. Notwithstanding Paragraph 5 and Paragraph 6, a party may disclose Confidential or Highly Confidential information at a deposition, a hearing, or at trial to: (i) any employee of the producing party; (ii) any person, no longer affiliated with the producing party, who authored or received the information in whole or in part; (iii) any person who, based on evidence, is reasonably believed to have had access to or knowledge to the information before these Actions were filed; (iv) a producing party's designee under Federal Rule of Civil Procedure 30(b)(6); and

(v) any person to whom the producing party consents to such disclosure in writing or orally on the record.

10. A party who wishes to disclose Confidential or Highly Confidential information to a person not authorized under Paragraph 5 or Paragraph 6 of this Protective Order to receive such information must first make a reasonable attempt to obtain the producing party's permission by serving a written request upon counsel for the producing party before the date of the proposed disclosure. Such request shall specifically identify the Confidential or Highly Confidential information, including production number, sought to be so disclosed and the name, title and function of the person(s) to whom such disclosure is desired to be made. The producing party shall thereafter respond to the request in writing within ten (10) business days after receipt of same. Absent good cause shown, a failure to respond within such time shall constitute consent to the request. If, where consent has been withheld, the parties are subsequently unable to agree on the terms and conditions of the requested disclosure, the matter may be submitted to the Court for resolution by the party seeking disclosure. Such disclosure shall be postponed until a ruling has been obtained from the Court.

11. A person may designate information in deposition testimony as Confidential or Highly Confidential by stating on the record at the deposition that the information is Confidential or Highly Confidential or by advising the opposing party and the stenographer and videographer in writing by page and line number during the 25-day period described herein that the information is Confidential or Highly Confidential. Whether or not a designation is made at the time of a deposition, all deposition testimony shall be treated as Highly Confidential from the taking of the deposition until twenty-five (25) days after receipt by deponent or deponent's counsel of the final transcript. If no such designation is made during the deposition or during the

25-day period, the deposition testimony shall not be treated as Confidential or Highly Confidential information unless otherwise agreed by the parties, ordered by the Court, or designated in accordance with Paragraph 14 of this Protective Order. At any deposition, to the extent Confidential or Highly Confidential documents are used or Confidential or Highly Confidential information is discussed, at the request of either party, the room will be closed to anyone other than the individuals designated to have access to such information pursuant to Paragraphs 5 and 6 of this Protective Order unless otherwise agreed upon by the parties on a deposition-by-deposition basis.

12. If counsel for a party receiving documents or information designated as Confidential or Highly Confidential hereunder objects to such designation of any or all of such items (or portions thereof), the following procedure shall apply:

a. Counsel for the objecting party shall serve on the designating party or third party a written objection to such designation, which shall describe with particularity the documents or information (or portions thereof) in question and shall state the grounds for objection. Counsel for the designating party or third party shall respond in writing to such objection within ten (10) business days, and shall state with particularity the grounds for asserting that the document or information (or portions thereof) is Confidential or Highly Confidential. If the designating party or nonparty makes a timely response to such objection asserting the propriety of the designation, counsel shall then confer in good faith in an effort to resolve the dispute.

b. If a dispute as to a Confidential or Highly Confidential designation of a document or item of information cannot be resolved by agreement, the proponent of the designation being challenged shall present the dispute to the Court in accordance with Judge Sleet's Discovery Dispute Resolution procedure. The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute.

13. Any party filing with the Court any Confidential or Highly Confidential material shall make such filing under seal in accordance with Local Civil Rule 5.1.3, the United States District Court for the District of Delaware's CM/ECF procedures, and any other procedures required by the Court. The burden of proving to the Court that such material should be sealed shall at all times remain with the party that initially disclosed and designated the subject material as Confidential or Highly Confidential under the terms of this Protective Order. If the filing party is not the designating party and is unaware of the specific basis for the designating party's having designated the subject material as Confidential or Highly Confidential, then the filing party nonetheless is obligated to make a reasonable effort when filing the subject material to seal such material. In the event the filing party takes exception to any designation of the subject material by the designating party, then the filing party shall seek relief from such designation pursuant to the procedures set forth in this Protective Order.

14. To the extent consistent with applicable law, the inadvertent or unintentional disclosure of Confidential or Highly Confidential material that should have been designated as such, regardless of whether the information, document or thing was so designated at the time of disclosure, shall not be deemed a waiver in whole or in part of a party's claim of confidentiality, either as to the specific information, document or thing disclosed or as to any other material or

information concerning the same or related subject matter. Such inadvertent or unintentional disclosure may be rectified by notifying in writing counsel for all parties to whom the material was disclosed that the material should have been designated Confidential or Highly Confidential within a reasonable time after the discovery of such inadvertent disclosures. Such notice shall constitute a designation of the information, document or thing as Confidential or Highly Confidential under this Protective Order.

15. When the inadvertent or mistaken disclosure of any information, document or thing protected by privilege or work-product immunity is discovered by the producing party and brought to the attention of the receiving party, the receiving party's treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5)(B). Such inadvertent or mistaken disclosure of such information, document or thing shall not by itself constitute a waiver by the producing party of any claims of privilege or work-product immunity. However, nothing herein restricts the right of the receiving party to challenge the producing party's claim of privilege if appropriate within a reasonable time after receiving notice of the inadvertent or mistaken disclosure.

16. Patent Prosecution. Any individual in-house or outside counsel who receives or reviews Confidential and/or Highly Confidential information shall not, during the pendency of the Actions, manage or participate in the preparation or prosecution (not including post-grant proceedings) of any receiving party's patent application before the U.S. Patent & Trademark Office or any corresponding foreign patent authority that involves pharmaceutical products containing icatibant. Any individual in-house or outside counsel who receives or reviews Confidential and/or Highly Confidential information may participate in post-grant proceedings (including inter partes review, post-grant review, interference, covered business method review,

opposition or nullity or revocation proceedings, or ex parte reexamination) before the U.S. Patent & Trademark Office, or corresponding proceedings before any foreign patent authority, with the exception that the individual in-house or outside counsel who receives or reviews Confidential and/or Highly Confidential information shall not participate, directly or indirectly, in the drafting or amendment of claims broader in scope than existing claims concerning any party's patent that involves pharmaceutical products containing icatibant.

17. No information that is in the public domain or which is already known by the receiving party through proper means, or which is or becomes available to a party from a source other than the party asserting confidentiality, where such source is rightfully in possession of such information on a non-confidential basis, shall be deemed or considered to be Confidential or Highly Confidential material under this Protective Order.

18. Upon receipt of any request or subpoena for Confidential or Highly Confidential material, the party receiving the request or subpoena shall immediately notify outside counsel of record for the producing party of the request or subpoena, so that the latter may protect its interests.

19. This Protective Order shall not deprive any party of its right to object to discovery by any other party or on any otherwise permitted ground. This Protective Order is being entered without prejudice to the right of any party to move the Court for modification of or for relief from any of its terms.

20. Within sixty (60) calendar days of the conclusion of these Actions, including all appeals, each party or individual subject to the terms hereof must either return to the producing party or destroy all documents and copies of documents containing the producing party's Confidential or Highly Confidential information, and must destroy all notes, memoranda, or

other materials derived from or in any way revealing such information. The party returning and/or destroying the producing party's Confidential and Highly Confidential information must promptly certify in writing its compliance with the requirements of this Paragraph. Notwithstanding the foregoing, outside counsel for a receiving party may retain Confidential and Highly Confidential information to the extent such information is contained in counsel's work product, correspondence between outside counsel, or in copies of pleadings and materials exchanged during discovery or submitted to the Court, subject to the confidentiality provisions of this Protective Order.

21. The United States District Court for the District of Delaware is responsible for the interpretation and enforcement of this Protective Order. All disputes concerning Confidential or Highly Confidential material produced under the protection of this Protective Order shall be resolved by the United States District Court for the District of Delaware. Every individual who receives any Confidential or Highly Confidential material agrees to subject himself or herself to the jurisdiction of this Court for the purpose of any proceedings related to performance under, compliance with, or violation of this Protective Order.

22. This Protective Order has been agreed to by the parties to facilitate discovery and production of relevant evidence in the above-captioned Actions. Neither the agreement of the parties, nor the designation of any information, document, or the like as Confidential or Highly Confidential information, nor the failure to make such designation, shall constitute evidence with respect to any issue in the above-captioned Actions.

23. This Protective Order shall survive the termination of these Actions and shall remain in full force and effect unless modified by an Order of this Court or by the written stipulation of the parties filed with the Court.

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May 12, 2016

SO ORDERED this ___ day of ______________, 2016.

____
The Honorable Gregory M. Sleet
United States District Judge

10031157

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE ORPHAN THERAPIES LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH,	)	
Plaintiffs,	)	
v.	)	C.A. No. 15-1102 (GMS) CONSOLIDATED
FRESENIUS KABI USA, LLC and SANDOZ INC.,	)	
Defendants.	)	

AGREEMENT TO BE BOUND BY STIPULATED PROTECTIVE ORDER

I, ______________________________, being duly sworn, state that:

1. My address is ____.

2. My present employer is __________________________ and the address of my present employment is ____.

3. My present occupation or job description is ______________________________.

4. I have carefully read and understood the provisions of the Protective Order in these Actions signed by the Court, and I will comply with all provisions of the Protective Order.

5. I will hold in confidence and not disclose to anyone not qualified under the Protective Order any Confidential or Highly Confidential material, or any words, summaries, abstracts, or indices of Confidential or Highly Confidential material disclosed to me.

6. I will use Confidential or Highly Confidential material disclosed to me solely for purposes relating to these Actions.

7. No later than the final conclusion of these Actions, I will return or destroy all Confidential or Highly Confidential material and summaries, abstracts, and indices thereof which

come into my possession, and documents or things which I have prepared relating thereto, to counsel for the party for whom I was employed or retained.

8. I declare under penalty of perjury that the foregoing is true and correct.

Signed: ______________________________ Dated: ______________________

Printed Name: _________________________